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HUBR 1159 (10016584)

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. BOX 1450, Alexandria VA 22313-1450, on the date shown below.

Dated: 2/2/05 Signature: _____ (Evelyn Rosario)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Josef BURG et al.

Application No.: 09/555,950 Group Art Unit: 1654

Filed: August 17, 2000 Examiner: Maury A. Audet

For: ERYTHROPOIETIN WITH SPECIFIC ACTIVITY

RESPONSE TO OFFICE ACTION
(37 CFR § 1.111)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

This is submitted in response to the office action of September 9, 2004. A two month extension of time is required, and a petition therefore, with fee, accompanies this response.

Claims 88-99, 101, 103 and 104 are pending. All of these claims have been rejected over 35 USC §102(b), (e) and 35 USC §103 in view of Watson, et al., Glycobiology 4(2): 227-37 (1994); Takeuchi, et al., Proc. Natl. Acad. Sci. USA 86: 7810-7822 (1984); Blumen, et al., U.S. Patent No. 5,459,031; Akamatsu, et al., U.S. Patent No. 4,745,099; Strickland, et al., U.S. Patent No. 5,856,298.

The examiner appears to accept that none of these references teach the recombinant production of EPO in human cells. Yet, the examiner posits that EPO

produced in CHO cells – which is what each and every reference teaches – must inherently teach what is claimed.

First, inherency is a basis for an anticipation reference if and only if the reference teaches that what is clamed is the inevitable and necessary result of what is taught in the prior art. While the references teach production of EPO, there is no showing or suggestion of at least 4.3 N acetyl lactosamine units per N-linked carbohydrate, or an average of 13.0 N-acetyl lactosamine units, as referred to total N-glycosylation, nor of carbohydrates with N-acetyl lactosamine units of at least 10%.

Evidence provided in the specification clearly and unequivocally establishes that human and non-human cells DO NOT produce the same EPO. Please see page 51 of the specification table 4, comparing three non-human samples (CHO) with five human samples (HeLa).

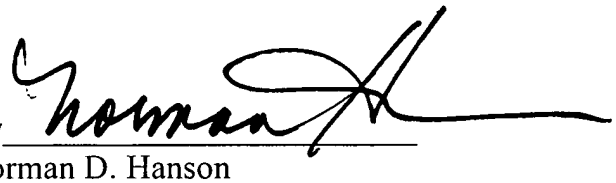
Note, especially, that if one were to compare CHO1 with HeLa1, where the degree of tetrantennarity and NaLa units are in fact, essentially the same. For the EPO produced in human cells, a repeat percentage of 18 was sufficient for activity of 220 ku/mg. CHO1 required 39.6 for 248 ku/mg. The difference of 28 ku/mg is not explanable by repeats only. One must conclude that there is a fundamental difference between EPO produced in human and non-human cells.

Indeed, when one compares CHO2/HeLa2 or HeLa3, or CHO3/HeLa4, the parameters differ by about 15%. When repeat percentages are compared, however, CHO2 shows 51% as compared to 16.5 and 14%, (HeLa 2 and 3), while CHO3 shows 42.6%, as Compared to 12.2% (HeLa4) -- a variance of 220-360%, for essentially equal activity.

The facts show that the molecules are NOT the same, and there is absolutely no suggestion that one could routinely and obviously secure molecules from human cells, with the recited properties.

In view of this, it is asserted that the claimed subject matter cannot be deemed anticipated or obvious in view of the cited references and be holding to that end, by way of a notice of allowance, is requested.

Respectfully submitted,

By 

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket No. (Optional) HUBR 1159 (10016584)

In re Application of	BURG, ET AL
Application Number 09/555,950	Filed AUGUST 17, 2000
For:	ERYTHROPOIETIN WITH SPECIFIC ACTIVITY
Art Unit 1654	Examiner MAURY A. AUDET

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

[ ]	One month (37 CFR 1.17(a)(1))	$
[X]	Two months (37 CFR 1.17(a)(2))	$ 450.00
[ ]	Three months (37 CFR 1.17(a)(3))	$
[ ]	Four months (37 CFR 1.17(a)(4))	$
[ ]	Five months (37 CFR 1.17(a)(5))	$

[ ] Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ _____ .

[X] A check in the amount of the fee is enclosed.

[ ] Payment by credit card. Form PTO-2038 is attached.

[ ] The Director has already been authorized to charge fees in this application to a Deposit Account.

[x] The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0624 .

I have enclosed a duplicate copy of this sheet.

I am the

[ ] applicant/inventor.

[ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

[ ] attorney or agent of record. Registration Number _____

[x] attorney or agent under 37 CFR 1.34(a).

Registration number if acting under 37 CFR 1.34(a) 30,946

2/2/05
Date

Signature

(212) 318-3168
Telephone Number

Norman D. Hanson
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below

[ ] Total of _____ forms are submitted.

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